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67

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26646	7590	07/22/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 07/22/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,935

Applicant(s)

PALASIS, MARIA

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/2/04; 9/27/04; 4/29/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-60, 62-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-60, 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 54-55, 58-60 and 62-64 are pending.

Applicant's traversal, the cancellation of claim 61, the addition of claims 63-64, and the amendment to claims 60 and 62 filed on 9/2/04 is acknowledged and considered by the examiner. However, the claims contain an improper status identifier and a non-responsive letter was mailed to applicant on 9/13/04.

Applicant responded to letter on 9/27/04. However, the claims contain an improper status identifier and another non-responsive letter was mailed to applicant on 4/7/05.

Applicants responded to letter on 4/29/05 with a status identifier for claims that is considered proper. The amendment was entered and considered by the examiner.

Election/Restrictions

Newly submitted species in claim 60 and 62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: applicants elected without traverse species angiogenic agent on 10/4/02.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, species (2)-(35) in claim 60 and species (2)-(37) in claim 62 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Instant claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 54-55, 58-60 and 62-64 are unsupported under 35 U.S.C. 112, first paragraph, as failing to comply with the 112 first paragraph written description.

The original specification (09/204,254 filed 12/3/98, now US 6,369,039) did not disclose making and using a medical device comprising a biocompatible structure carrying a genetic material, said biocompatible structure comprising an angiogenic agent selected from acidic fibroblast growth factor, basic fibroblast growth factor, vascular growth factor, epidermal growth factor, transforming growth factor alpha and beta, platelet-derived growth factor, platelet-derived growth factor, tumor necrosis factor alpha, hepatocyte growth factor, or insulin growth factor. However, the list set forth in the new claims does not include all of the products listed in the specification that are considered angiogenic agents (hif-1 and NOS). The specification does not disclose the subgenus set forth in the amended and new claims and claims dependent therefrom. Thus, nothing in the specification would lead one to the particular combination set forth in the

Art Unit: 1635

amended and claims dependent therefrom and new claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Thus, the instant claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 54-55, 58-60 and 62-64 in the application do not enjoy priority to application '254 filed on 12/3/98.

Applicant's arguments filed 9/2/04 have been fully considered but they are not persuasive.

In response to applicant's argument that the original description of the '039 patent provides written description of a therapeutic agent and a vector encoding a polypeptide or protein selected from the above recited groups, as claimed (See col. 4, lines 64-67, Col. 5, lines 1-44, and Col. 5, line 62 through Col. 6, line 7), the argument is not found persuasive because the claims do not include all of the angiogenic agents listed in the specification of the '039 patent.

In response to applicant's argument that, "The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon **'reasonably conveys to the artisan that the inventor has possession at the time of the later claimed subject matter.'**" *Vas-Cath, Inc. v. Mahurkar* 935 F.2d 1555, 1563, (Fed. Cir. 1991), the argument is not found persuasive because there is no evidence of record that the list of angiogenic factors excluding NOS and hif-1 and any other angiogenic factors excluded from the claims was reasonably conveyed to the artisan at the time the later claimed subject matter was filed. See *Purdue Pharma L.P. v. Faulding Inc.* 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000) noting that

Art Unit: 1635

“with respect In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say “here is my invention.” In order to satisfy written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.” This is the case here, the applicant did not disclose using a list of angiogenic agents excluding hif-1, NOS and any other angiogenic agent listed in the instant specification from the subgenus listed in the instant claims.

Claim Objections

Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-59 are objected to because of the following informalities: the claims do not depend on a preceding claim.

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

If the claims become allowable, these claims would have to be amended to depend on a preceding claim.

Applicant is advised that should claim 37 be found allowable, claim 58 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

Art Unit: 1635

application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 54-55, 58-60 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 60 and 62 and new claims 63-64 filed on 9/4/04 introduce new subject matter into the application.

With respect to the limitation 'acidic fibroblast growth factor, basic fibroblast growth factor, vascular growth factor, epidermal growth factor, transforming growth factor alpha and beta, platelet-derived growth factor, platelet-derived growth factor, tumor necrosis factor alpha, hepatocyte growth factor, or insulin growth factor' in amended claims 60 and 62 new claims 63-64, the original specification did not disclose the limitation. The support cited for the newly added limitation to the claims does not provide support for the limitation. Page 17, line 20 through page 18, line 16 lists several angiogenic agents that are excluded from the list in the

Art Unit: 1635

instant claims. The instant specification does not disclose the subgenus set forth in the new claims and amended claims and claims dependent therefrom. It is apparent that the applicants at the time the invention was made did not intend or contemplate making and/or using the medical device set forth in the amended claims and claims dependent therefrom and newly added claims as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the medical device as set forth in the newly filed claims and amended claims and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments, see pages 12-13, filed 9/4/04, with respect to the rejection(s) of claim(s) 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54, 55, 58-62 under 112 first paragraph new matter have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the addition of claims 63-64 and amendment to claims 60 and 62.

Claim Rejections - 35 USC § 102

For the reasons set forth above, the instant claims only enjoy priority to 4/4/00 (date the instant application was filed).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claimed invention reads on making and using a medical device comprising a biocompatible structure (e.g., stent) comprising a polymeric coating that coats at least a portion of said structure and coating comprising an angiogenic agent and a vector containing a polynucleotide encoding one or more angiogenic agents, wherein the angiogenic agent can be an acidic fibroblast growth factor, basic fibroblast growth factor, vascular growth factor, epidermal growth factor, transforming growth factor alpha and beta, platelet-derived growth factor, platelet-derived growth factor, tumor necrosis factor alpha, hepatocyte growth factor, or insulin growth factor.

The limitation “wherein said expression is achieved in about 20% to about 80% of cells exposed to said genetic material” in instant claim 12 has little patentable weight over the prior art because the limitation does not describe a structural limitation that would differentiate the claimed medical device over a medical device embraced by the instant claims that is taught in the prior art. See MPEP 2111.02.

Claims 12, 17, 18, 19, 23, 24, 25, 42, 43, 44, 54, 55, and 59, 60, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. (US 5,879,713). Roth teaches delivering to a vascular system of an animal a biodegradable, biocompatible polymeric microparticles comprising biologically active molecules selected from the group consisting of growth factors, cytokines, angiogenesis factors, immunosuppressant molecules, peptide fragments thereof and nucleic acid constructs capable of synthesizing these compounds, wherein restenosis has occurred following balloon angioplasty (abstract and columns 10 and 16-18). Roth teaches the limitation in instant claims 24 and 25 (columns 10 and 16-18). The growth factors can be VEGF, bFGF, and PDGF and DNA encoding them (column 10). The biologically active

Art Unit: 1635

molecules, which are immobilized on the polymeric microparticles can include proteins, nucleic acid molecules, carbohydrates, lipids and combinations thereof (column 9). Roth teaches the limitation in instant claims 17 and 42 (columns 3-4). Roth teaches the limitation in instant claims 18 and 43 (column 11). Roth teaches the limitation in instant claims 19 and 44 (column 11). Roth teaches the limitation in instant claims 23 (columns 10-11 and 14). Roth teaches the limitation in instant claim 55 (column 9). Roth teaches the limitation in instant claims 54 and 59 because in order for the nucleic acid to be expressed in the animal a regulatory sequence is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 10, 11, 27, 34, 35, 36, 37, 58, 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al. (US 5,879,713) taken with Branellec et al. (US Patent No.

Art Unit: 1635

5,851,521, cited on a previous PTO-892). Roth teaches delivering to a vascular system of an animal a biodegradable, biocompatible polymeric microparticles comprising biologically active molecules selected from the group consisting of growth factors, cytokines, angiogenesis factors, immunosuppressant molecules, peptide fragments thereof and nucleic acid constructs capable of synthesizing these compounds, wherein restenosis has occurred following balloon angioplasty (abstract and columns 10 and 16-18). The growth factors can be VEGF, bFGF, and PDGF and DNA encoding them (column 10). The biologically active molecules, which are immobilized on the polymeric microparticles can include proteins, nucleic acid molecules, carbohydrates, lipids and combinations thereof (column 9). Roth teaches the limitation in instant claims 54 and 59 because in order for the nucleic acid to be expressed in the animal a regulatory sequence is required. However, Roth does not specifically making and using a viral vector (AAV) to deliver the nucleic acid to the area where restenosis occurred.

However, at the time the invention was made, replication defective AAV viral vectors were well known to one of ordinary skill in the art for delivering nucleic acid to cells using a catheter and using micro-particles (e.g. polylactide) to deliver said nucleic acid (column 9, line 60-column, line 67). Branellec teaches using AAV vectors comprising a protein in a method inhibiting restenosis in a mammal (abstract and column 7, lines 55-65). AAV vectors are able to infect a wide spectrum of cells without inducing any effect on cellular growth, morphology, or differentiation and they do not appear to be involved in human pathologies. Furthermore, the instant specification indicates that AAV was able to transform cells with >50% frequency (page 29). This would indicate to one of ordinary skill in the art that expression of the genetic material would be observed in <50% of the cells and read on the limitation of instant claim 36.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth taken with Branellec, namely to produce the microparticle comprising a replication defective AAV vector. One of ordinary skill in the art would have been motivated to combine the teaching and make the microparticle comprising a replication defective AAV vector because AAV vectors are well known to one of ordinary skill in the art to be non-pathogenic in vivo and infect a wide spectrum of cells without inducing any effect on cellular growth, morphology, or differentiation.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth taken with Branellec, namely to use a replication defective AAV vector in the microparticle for delivering a genetic material to a mammal. One of ordinary skill in the art would have been motivated to combine the teaching and use the replication defective AAV in the method because AAV vectors are non-pathogenic in mammals and are well known to one of ordinary skill in the art for delivering a nucleic acid to a mammal with restenosis as exemplified by Branellec (column 7).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth taken with Branellec, namely to make and/or use a replication defective AAV vector as a delayed expression vector. One of ordinary skill in the art would have been motivated to combine the teaching and use the replication defective AAV as a delayed expression vector because AAV vectors are required to transfect a cell and form ds DNA and then express the nucleic acid inside the cell, which would be considered to one of ordinary skill in the art a delayed expression vector (column 7).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 37, 38, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al. (US 5,879,713) taken with Branellec et al. (US Patent No. 5,851,521, cited on a previous PTO-892) as applied to Claims 3, 10, 11, 27, 34, 35, 36, 37, 58, 60 and 62 above, and further in view of Vincent-Lacaze et al. (Journal of Virology, March 1999, p. 1949-1955, Vol. 73, No. 3).

Roth taken with Branellec do not specifically teach that expression of a nucleic acid is delayed from about two days to about 3 weeks after in vivo administration of an AAV vector comprising the nucleic acid.

However, at the time the invention was made, Vincent-Lacaze et al. teach that it takes about several days for a nucleic acid to be expressed in vivo when delivered using an AAV vector (page 1950).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth and Branellec taken with Vincent-Lacaze to understand that it takes several days for a nucleic acid to be expressed in vivo by an AAV vector.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 19, 20, 44, 47, 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al. (US 5,879,713) taken with Donovan et al. (US 5,833,651, cited on a previous PTO-892). Roth teaches delivering to a vascular system of an animal a biodegradable, biocompatible polymeric microparticles comprising biologically active molecules selected from the group consisting of growth factors, cytokines, angiogenesis factors, immunosuppressant molecules, peptide fragments thereof and nucleic acid constructs capable of synthesizing these compounds, wherein restenosis has occurred following balloon angioplasty (abstract and columns 10 and 16-18). The growth factors can be VEGF, bFGF, and PDGF and DNA encoding them (column 10). The biologically active molecules, which are immobilized on the polymeric microparticles can include proteins, nucleic acid molecules, carbohydrates, lipids and combinations thereof (column 9). Roth teaches the limitation in instant claims 54 and 59 because in order for the nucleic acid to be expressed in the animal a regulatory sequence is required. However, Roth does not specifically making and using a metallic stent to deliver the nucleic acid to the area where restenosis occurred.

However, at the time the invention was made, Donovan teaches that metallic stents are well known to one of ordinary skill in the art for delivering microparticles to an area of a mammal (columns 5-6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth taken with Donovan, to make a metallic stent comprising the microparticle. One of ordinary skill in the art would have been motivated to combine the teaching, as a matter of designer's choice, and make a metallic stent comprising the

Art Unit: 1635

microparticle because metallic stents are well known to one of ordinary skill in the art for delivering a microparticle to an area of a mammal as exemplified by Donovan (columns 5-6).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Roth taken with Donovan, namely to use a metallic stent for delivering the microparticle to an area of a mammal. One of ordinary skill in the art, as a matter of designer's choice, would have been motivated to combine the teaching and use a metallic stent in the method because metallic stents are well known to one of ordinary skill in the art for sustainable delivery of microparticles to an area of a mammal as exemplified by Donovan (columns 5-6).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments, see page 14, filed 9/2/04, with respect to 112 second paragraph have been fully considered and are persuasive. The rejection of claims 60-62 has been withdrawn because of the cancellation of claim 61 and the amendment of claims 60 and 62.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1635

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

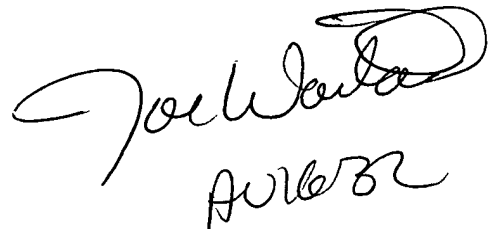
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Art Unit: 1635

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Brian Whiteman
Patent Examiner, Group 1635



Handwritten signature of Joel Winters, dated 10/16/02.